UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

LEAH ROYCE HINES,
Plaintiff,

v.

Civil Action No. 2:04-CV-0690
Honorable John T. Copenhaver, Jr.

WYETH (d/b/a WYETH, INC.;
WYETH PHARMACEUTICALS, INC.; and,
PHARMACIA & UPJOHN COMPANY,
Defendants.

PLAINTIFF'S RESPONSE TO DEFENDANTS' MOTION FOR DIRECTED VERDICT RE PROXIMATE CAUSATION

Defendants have argued that the Court should grant judgment as a matter of law for the Defendants because Mrs. Hines and her doctors did not testify that they relied on the labels that came with E+P.[1] However, Defendants overlook that there is no requirement in the law that Plaintiff or her doctor read the label; instead, the law requires that Defendants adequately warn of the risks of their drugs. In order to show proximate cause, Plaintiff must show that "an adequate warning would have changed behavior that would have avoided Plaintiff's injury." Def. Brief. at 1. Plaintiff testified that if she was warned of the risk of breast cancer, she would not have taken E+P. Her prescribing physicians similarly testified that had they been aware of a risk of breast cancer, they would have informed their patients of that risk when prescribing E+P. Thus, *any* adequate warning Defendants provided would have prevented Mrs. Hines from getting breast cancer, yet Defendants did not provide one.

Defendant drug manufacturers have a variety of avenues available to them to warn patients of the risks of their drugs. Manufacturers can convey information to patients and

[1] To be clear, Defendants request a directed verdict on the issue of proximate causation, but this motion only applies to proximate causation in the failure to warn (rather than the issue of whether Defendants' E+P drugs proximately caused Mrs. Hines' breast cancer). Thus, Plaintiff has restricted this response to the issue of proximate causation with regard to failure to warn.

doctors through promotional materials, Dear Doctor letters, and informational material left in the office by sales representatives. Plaintiff's doctors testified that they receive risk/benefit information about drugs in these various ways, as well as through medical literature and attending conferences. Defendants took none of these opportunities to inform doctors or patients of the true risk of breast cancer, and thus, a jury can find that Defendants' failure to warn proximately caused Mrs. Hines' breast cancer. The record also makes clear that when doctors do receive this type of reliable risk information, as they did with the WHI, their practices do change.

LEGAL STANDARD FOR JUDGMENT AS A MATTER OF LAW

Pursuant to Federal Rule of Civil Procedure 50(a), "[a] court may award judgment as a matter of law *only* if there is no legally sufficient evidentiary basis for a reasonable jury to find for the non-moving party." *Saunders v. Branch Banking & Trust Co., of Va.,* 526 F.3d 142, 147 (4th Cir. 2008) (emphasis added). Motions for judgment as a matter of law are highly disfavored because they intrude on the rightful province of the jury. *Boodoo* v. *Cary,* 21 F.3d 1157, 1161 (D.C. Cir. 1994).

When deciding a motion for judgment as a matter of law, the Court should review all of the evidence in the record and draw all reasonable inferences in favor of the nonmoving party, while avoiding judgments on credibility. *Reeves v. Sanderson Plumbing Products, Inc.,* 530 U.S. 133, 150 (2000). "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). Thus, although the Court should review the record as a whole, it must disregard all evidence favorable to the moving party that the jury is not required to believe. *Reeves*, 530 U.S. at 151. In other words, there must be a complete absence of evidence or the evidence in favor of the moving party must be so overwhelming that no reasonable person

could arrive at a verdict against it. *Galdieri v. Nat'l Realty & Dev. Corp*., 136 F.3d 276, 289 (2nd Cir. 1998).

ARGUMENT

In order to prove proximate cause, Plaintiff need only show that Defendants' actions (or inactions) were *a* proximate cause of the plaintiff's injury, not the *sole* proximate cause. *Mays v. Chang*, 579 S.E.2d 561, 565 (W.Va. 2003). Plaintiff has presented sufficient evidence for a jury to conclude that the labels on Defendants' E+P drugs were inadequate,[2] and that had Mrs. Hines been warned of the risk of breast cancer, she would not have taken the drugs.

Such evidence makes judgment as a matter of law on proximate cause inappropriate. *See Mays*, 579 S.E.2d at 565. "Questions of negligence, due care, proximate cause and concurrent negligence present issues of fact for jury determination when the evidence pertaining to such issues is conflicting or where the facts, even though undisputed, are such that reasonable men may draw different conclusions from them." Syl. Pt. 3, *Mays*, 579 S.E.2d at 563 (citing Syllabus Point 5, *Hatten v. Mason Realty Co.*, 148 W.Va. 380, 135 S.E.2d 236 (1964)).

The Supreme Court recognized that proximate cause is an "elastic and mystical term that is meaningless unless it is applied to the facts of a particular case" that should be left to the jury to resolve. *Mays*, 579 S.E.2d at 565. In *Stewart v. George*, after the evidence was presented to the jury, the court held that "questions of proximate cause are often fact-based issues best resolved by a jury," and "[t]he uncertainties implicit in this medical record are prime territories for jury determination." 607 S.E.2d 394, 399 (W.Va. 2004).

Not only did Premarin and Provera labels not adequately warn Mrs. Hines or her doctors (*i.e*., the labels were silent on E+P and breast cancer from 1994-98), but neither she nor her

[2] *See* Plaintiff's Response to Mtn. for Directed Verdict on Failure to Warn, which Plaintiff incorporates herein.

doctors were warned of a significant risk of breast cancer from E+P from any other source. Defendants had numerous opportunities to educate the medical community, including but not limited to Dear Doctor letters, visits by sales representatives to doctors' offices, press releases, and sponsoring of CME curricula. However, Defendants never provided warnings in any of these contexts.[3]

I. PLAINTIFF HAS PRESENTED SUFFICIENT EVIDENCE FOR A JURY TO FIND THAT AN ADEQUATE WARNING WOULD HAVE PREVENTED MRS. HINES FROM GETTING BREAST CANCER

In order to prove proximate causation under a failure to warn claim, plaintiff need only show that a better warning would have altered the prescribing practices of plaintiff's physician, or otherwise caused Mrs. Hines not to take E+P.

A. IN ORDER TO SHOW PROXIMATE CAUSATION, PLAINTIFF NEED ONLY PROVE THAT AN ADEQUATE WARNING WOULD HAVE CHANGED HER DECISION TO TAKE THE DRUG (OR HER DOCTORS' DECISION TO PRESCRIBE THE DRUG) – ***NOT*** THAT SHE RELIED ON THE PACKAGE INSERT

Contrary to Defendants' argument regarding reliance on the label, there is no legal requirement that patients and doctors must read labels. Def. Brief at 1. Plaintiff is only required to prove that had she (or her doctor) obtained an adequate warning, she would have decided not to take the drug (or her doctor would have decided not to prescribe the drug).

The Defendants' heavy focus on the actual package insert (or PDR) is unduly narrow. *See V. E. Irons, Inc. v. United States*, 244 F.2d 34, 39 (1st Cir.), *cert. denied*, 354 U.S. 923 (1957) (all literature used in the sale of food and drugs constituted 'labeling' within the statutory definition, and thus may properly be received in evidence as proof of false or misleading statements."). Plaintiff testified that if she had been warned about the risk of breast cancer in any

[3] Plaintiff further refers the Court to her Fact Statement in Support of Plaintiff's Oppositions to Defendants' Motions for Judgment filed separately.

way, she would not have taken the drugs. (Trial Tr. at 1410:1-4; 1451:20 – 1452:8.)[4] Similarly, based on her doctors' testimony, a jury could conclude that if her doctors they had been adequately warned about the risk of breast cancer, they would not have prescribed the drugs. For example, news of the WHI radically changed doctors' E+P prescribing habits nationwide, as well as that of Mrs. Hines' doctor (Dr. Lotshaw) – even though Dr. Lotshaw says he did not read the E+P labels. (Trial Tr. at 1478:23-24 (Dr. Lotshaw testified that his prescribing practices dramatically changed with the publication of the WHI); 1473:22 – 1475:4). Similarly, Dr. Stevens testified that he would pass on risk/benefit information to patients, so if a WHI study had been done by Defendants' earlier, before Dr. Stevens had retired in 1997, it would have affected his practice. (Trial Tr. 1239:10-16.) Defendants' brief rests on the false assumption that the only way Plaintiff or her doctors could have received a warning was through the package insert, and thus, their motion must be denied.

Whether Defendants' inadequately warnings proximately caused Mrs. Hines breast cancer is a fact question that should be resolved by the jury, not as a matter of law. *See Stewart*, 607 S.E.2d at 399 ("questions of proximate cause are often fact-based issues best resolved by a jury").

B. DOCTORS ARE COMMONLY WARNED OF THE RISKS OF DRUGS THROUGH SOURCES OTHER THAN THE PDR

The idea that the only way to warn physicians of the risks of drugs is by putting a warning in the PDR is simply false. All information that drug manufacturers provide to doctors and patients is "part of the label" and considered part of the warning provided to physicians and doctors. *See, e.g.*, *V. E. Irons*, 244 F.2d at 39 (all literature used in the sale of food and drugs constituted 'labeling' within the statutory definition, and thus may properly be received in

[4] All references to the Trial Transcript in this memorandum refer to the Rough Draft, as the final version is not yet available.

evidence as proof of false or misleading statements."). For instance, the FDA allows drug manufacturers to send "Dear Doctor" letters when new and important safety information is discovered. *See* Fact Statement in Support of Plaintiff's Oppositions to Defendants' Motions for Judgment, Section B and D.

Dr. Parisian explained to the jury that what a manufacturer says at meetings, what it gives to doctors as handouts, information it provides in Dear Doctor letters, and information supplied by the manufacturer that is posted in a drugstore, are all considered part of the manufacturer's warnings. (Trial Tr. at 336:6-21.) Surely, if Defendants had announced in a press release that E+P causes breast cancer, or provided pamphlets to doctors that said that, or developed CME curricula that said that (or had taken any combination of these steps) (but had not stated that risk in the E+P label), Defendants would not be arguing that the only way they could convey a warning would be through the product label. Drug manufacturers have many avenues to convey safety information to doctors and the public, and yet Defendants took none of these opportunities to provide an appropriate warning.

The jury has heard evidence, that doctors can obtain risk/benefit information from other sources. Dr. Stevens testified that he received information about drugs from pharmaceutical representatives and the information the representatives left in the office. (Trial Tr. at 1231:5-19.) He testified that he attended medical conferences, and reviewed available information about cancer at the Tumor Board. (Trial Tr. at 1231:20-25; 1215:3-19.) Defendants could have used any one of these means to get Dr. Stevens a warning that their E+P drugs caused breast cancer. In fact, Dr. Parisian explained that drug manufacturers are required under the FDA to make sure they get important warning information to doctors. (Trial Tr. at 336:6-21.)

Tellingly, Dr. Stevens thought that E+P had cardiovascular benefits, but such benefits had never been indicated in the label. (Trial Tr. 1235:2-6.) Clearly, Dr. Stevens obtained risk/benefit information from sources other than the PDR. Had Defendants put information into other communication channels they controlled that their drugs caused breast cancer, Plaintiffs' doctors would have picked it up, and passed it along to their patients. Dr. Stevens testified that had he been warned of the risk of breast cancer, he would have provided such information to his patients. (Trial Tr. 1239:10-16.) Knowing the findings of the WHI, Dr. Lotshaw now requires patients to sign informed consent forms to inform them of the risk, and does not recommend .625/25 of estrogen plus progestin. (Trial Tr. at 1483:8-24.) He prescribes the drugs far less; his IMS data proves this. (Trial Tr. at 1484:9-21; PX 9204.) He changed his prescribing practices after the WHI because he was fully warned of the risk of breast cancer for the first time – and not by the PDR. He testified that he does not really review the PDR, and yet he is now aware of the risk of breast cancer from E+P. (Trial Tr. 1473:22 – 1475:4.) Thus, he must have obtained the information that E+P causes breast cancer from another source of information, defeating Defendants' argument that proximate cause turns only on information obtained through the label. The evidence shows that Defendant could have done a WHI-type study or other breast cancer studies years earlier to improve the reliability of their warnings. They chose not to do so. *See* Fact Statement in Support of Plaintiff's Oppositions to Defendants' Motions for Judgment, Section B and D.

Defendants admit that "a plaintiff must establish that an adequate warning would have changed behavior in a manner that would have avoided the plaintiff's injury." Def. Brief. at 1. The evidence Plaintiff has presented that a warning in any context would have changed her

behavior is sufficient for a jury to conclude that Defendants failure to warn proximately caused Plaintiff's injury.

Further, if Defendant drug manufacturers had added black box warnings to the E+P labels to warn about breast cancer (as they did with Premarin and uterine cancer), prescribers – even those that do not rely on the label – would have heard that information through various channels. Under FDA regulations, (specifically Changes Being Effected) Defendants could have issued a stronger warning without prior FDA approval including a black box. *See* 21 CFR 314.70; Trial Tr. 488:17-25 (Parisian testimony that drug companies can strengthen their warning at any time without FDA approval). Defendants chose not to do so.

Further, a jury could reasonably find that if Defendant drug manufacturers conducted monitoring activities, including conducting a test like the WHI (which it was permitted to do) they would have learned of the risk of breast cancer sooner, and a stronger warning label would have been required, and the information could have been sent out through other channels.

The evidence shows that Defendants failed to avail themselves of any of these channels to provide an adequate warning, and that if they had, it is more likely than not that Plaintiff's doctors would not have prescribed the drug, and Plaintiff would not have taken it.

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CERTIFICATE OF SERVICE

The undersigned certifies that on this 24th day of July, 2011, the foregoing document was filed electronically on behalf of Plaintiffs with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record, as follows:

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